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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/740,821	12/21/2000	Daniel C. Carter	P06896US00/BAS	6567
881 7590 03/28/2007 STITES & HARBISON PLLC 1199 NORTH FAIRFAX STREET SUITE 900 ALEXANDRIA, VA 22314			EXAMINER LIU, SAMUEL W	
			ART UNIT	PAPER NUMBER
			1656	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/28/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

09/740,821

Applicant(s)

CARTER, DANIEL C.

Examiner

Samuel W. Liu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 50-56 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 50-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

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## **DTAILED ACTION**

### *Status of claims*

Claims 50-56 are pending.

The amendment filed 1/16/07 which cancels claims 1-49, and adds claims 50-56 (drawn into the elected invention) been entered. Also, the applicant's request (filed 1/16/07) for extension of time of three months has been entered. Claims 50-56 are examined in this Office action.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

### *Withdrawal of claim rejections*

- The rejections under 35 USC 102 to (i) claims 39, 43 and 49 by Mausner et al.; and (ii) claims 39, 41-43 and 47 by Nielson et al. are now withdrawn in light of cancellation of the claims thereof.

- The rejections under 35 USC 103(a) to (i) claims 39-40, 43 and 49 by Mausner et al., Miller et al. and Maki et al.; and (ii) claims 39-40, 41-43 and 47 by Nielson et al., Miller et al. and Maki et al. are now withdrawn in light of the cancellation of the claims thereof.

### *New- Objection to claim*

Claim 53 is objected to as being dependent from canceled claim 39. claim 53 may be rewritten to depend from claim 50.

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In claim 50, line 5, “ between “agent” and “vehicle”, a comma “,” should be inserted in order to be consistent with the recitation “agent, vehicle” (line 3).

***Claim Rejections - 35 USC § 112, the second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 50-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 is unclear whether or not vehicle, carrier and/or excipient are the cleansing agent. The dependent claims are also rejected.

***New-Claim Rejections - 35 USC §102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 54-56 are rejected under 35 U.S.C. 102(b) as anticipated by Mausner, J. (US Pat. No. 5254331).

In the patent claim 6, Mausner teaches a skin cream composition comprising human serum albumin (see item *i*). In Table I, Mausner teaches that said skin cream comprises: (i) steareth-21 which is a surfactant (see “*Discussion of art*”) about 1.3%-1.7% of the composition,

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and (ii) “ ascorbyl palmitate (about 0.7%, see item *m*), which is a typical surfactant or detergent (see “*Discussion of art*”). Since the detergent in said composition acts as a cleaning agent (detergent), the Mausner’s teachings therefore anticipate instant claim 54.

On column 7, line 3, Mausner teaches that the protein complex comprises about 28% serum protein (note that the patent claim 1 recites that the serum protein is human serum albumin). In the patent claim 1, item *d*, Mausner teaches that the protein complex comprises about 6.9% of the skin cream composition (total protein), i.e., the human serum albumin (HSA) comprises 1.9% (calculated from  $28\% \times 6.9\%$ ) of said composition. 1.9% is equivalent to 1.9 g per 100g, or approximately to 1.9 g per 100 ml of said skin *cream* composition, i.e., 19 mg/ml (calculated from 1900 mg/100 ml) of HSA in said composition. This meets the claim limitation “1 to 10 mg/ml” of HSA, and thus, the above Mausner’s teaching anticipates claims 55-56.

*Applicants’ Response to the rejection under USC 35 102(b)*

On page 3, 3<sup>rd</sup> paragraph, the response filed 1/16/07 argues that the ascorbyl palmitate is present in the Mausner’s composition as minus amount (0.01 to 0.03 percent) which is not sufficient for cleansing purpose, and argues that soap is different than a detergent (4<sup>th</sup> paragraph), and that use of the terms “soap”, “detergent” and “surfactant” interchangeably is incorrect (page 4, 1<sup>st</sup> paragraph) as the “surfactants” are commonly used as emulsifiers (see lines 6-7, 1<sup>st</sup> paragraph, page 4). Thus, the response infers that the rejection (if applicable to the new claims) should be withdrawn.

The applicant’s arguments are found to be unpersuasive because, as discussed above, the ascorbyl palmitate is present ~ 0.7% in the composition which is not minus amount but rather an

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amount allowing it to function as cleansing agent in the composition. It is burden to Applicant to show that this amount of the ascorbyl palmitate is insufficient for the cleansing thereof.

Moreover, Mausner has taught the surfactant steareth-21 (see "*Discussion of art*") having about 1.3%-1.7% of the composition.

Soap by definition is a surfactant or detergent (see PTO-892 mailed 11/3/05, "Kiwi Web"), i.e., soap and surfactant or detergent are mutually inclusive/exchangeable. The submission that surfactant is an emulsifier, and emulsifier can also be used as a surfactant may be true as seareth-21 can act as either surfactant (see Example 1, col. 5, Maurin et al.) or emulsifier (see page 3, Flexall Product Support (2007, updated) [http://www.ari-med.com/flexall\\_product\\_support.php](http://www.ari-med.com/flexall_product_support.php), pages 1-3). In the above discussed Mausner' composition, the cleansing agent (i.e., surfactant steareth-21) counts for 1.3%-1.7% of the composition together with 0.7% of ascorbyl palmitate would suffice said composition being a cleansing composition. Therefore, the above rejections are proper.

#### ***New-claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mausner, J. (US Pat. No. 5254331) in view of Miller, D. G. (EP 0180968) and Tarelli et al. (*Biologicals* (1998) 26, 331-346).

The rejection to claims 54-56 by Mausner has been discussed above.

As the obviousness prior art, the Mausner et al. reference also are applicable to instant claims 50 and 53. Also, Mausner et al. teach that their cosmetic composition is dispersed in the water (i.e., liquid phase). Because the composition contains the detergents: steareth-21 and ascorbyl palmitate (the patent claim 6) which must be dissolved in the water, and because the protein complex comprising HSA is dissolved in the water, HSA protein is thus dissolved in water aqueous phase, as applied to instant claims 51-52.

Yet, Mausner does not expressly teach that HAS is recombinant HSA.

Miller teaches that the recombinant human serum albumin (RHA) which is produced by expressing a cloned gene for HAS (see the patent claim 8) is useful as a cosmetic component, i.e., as a skin antiwrinkle agent (see abstract and the patent claims 1-4), as applied to claims 50-53.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute RHS for HSA in the Mausner's cosmetic composition. One skilled in the art would have been motivated to do this because Miller has taught usefulness of RHA as a skin antiwrinkle agent (see page 2, lines 16-18). Also, this is because the recombinant HAS, which can act as a suitable stabilizer, overcomes the drawbacks associated with non-recombinant HSA such as contamination with human pathogens and enzymes, structural heterogeneity and batch-to-batch variability, as taught by Tarelli et al. (see page 332, right column, lines 1-10). Thus, one skilled in the art would have preferably chosen the recombinant HSA and formulated it in the cosmetic composition with reasonably expected success.

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Therefore, the claimed invention was *prima facie* obvious to make and use the invention at the time it was made.

*Applicant's response to the rejection under USC 35 103(a)*

On pages 6-8, the response filed 1/16/07 submits that Miller reference is directed to an antiwrinkle preparation comprising HSA which preparation does not contain the cleansing agent (page 6, 2<sup>nd</sup> paragraph). Additionally, the response argues that although there is the motivation to use of recombinant HSA, no teaching/disclosure suggests that recombinant HSA can be used in the cleansing composition as claimed (page 6, lines 13-22). Thus, the response infers that the combination of the references (Mausner et al. and Miller) fails to teach or suggest that the safer and more effective recombinant albumin can be employed (see page 6, the last two lines), and therefore, the applicants request to withdrawn the rejection (if applied to the new claims).

The applicant's arguments are found unpersuasive because Miller pare serves as a secondary reference to show the motivation of the recombinant HAS which s useful for skin antiwrinkle. The recombinantly produced HSA has no the drawbacks (e.g., contamination with human pathogens and structural heterogeneity, as taught by Tarelli et al. above) of non-recombinant HSA protein. Thus, the safe and effectiveness of the recombinant albumin protein are not issue herein. The recombinant HSA would have been the first choice for preparing the cosmetic composition discussed above. Therefore, the rejections are proper.

***Conclusion***

No claims are allowed.

*Discussion of the art*



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The prior art made of record and not currently relied upon in any rejections is considered pertinent to Applicants' disclosure:

- Tree of Life Product (2007, updated) <http://www.tarahill.com/treeolif/ingred.html>, pages 1-2) teaches that soap is made from detergent sodium laurate which is a cleansing agent derived from coconut oil (page 1).
- Palma et al. (cited in PTO-892 mailed 11/3/2005) teach that ascorbyl palmitate is a string surfactant.
- Maurin et al. (US Pat. No. 6488928 B1) teach that Steareth-21 is a surfactant (see col. 5, Example 1, lines 28).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

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The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

*swl*

Samuel Wei Liu, Ph.D.

Patent Examiner, AU1653

March 12, 2007

*Kathleen Kerr Bragdon*

KATHLEEN KERR BRAGDON, PH.D.  
SUPERVISORY PATENT EXAMINER